K080128

510(K) SUMMARY
SM-Extra Wide(RBM) Implant System

MAY 14 2008

1. Submitter

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2. US Agent / Contact Person

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CA 90010, USA
Phone : 213-365-2875, Fax : 213-365-1595

3. Date Prepared

January 08, 2008

4. Device Name

SM-EXTRA WIDE(RBM) IMPLANT SYSTEM

5. Classification Name

Endosseous Dental Implant System

6. Device Classification

Class II
Dental Devices panel
Regulation Number: 21 CFR 872.3640

7. Predicate Devices

Rescue Internal Dental Implant System (510(k) No.: k063216)

8. Performance

Laboratory testing was conducted to determine device functionality and conformance to design input requirements.

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9. Device Description

SM-Extra Wide(RBM) Implant System consists of SM-Extra Wide(RBM) fixtures, abutments, prosthetics and surgical instruments.

SM-Extra Wide(RBM) Implant Fixtures are made of commercial pure titanium, grade 4 which have a sand-blasted, RBM(Resorbable Blast Media) treated surface. These fixtures are the one-stage implant and two-stage implant and surgically inserted in the maxillary or mandibular molar areas or where smaller implants have failed.
These fixtures are the integrated system of endosseous dental implants which designed to Provide prosthetics support for dental restoration (Crown, Bridges, and overdentures) in partially or fully edentulous individuals.

The screw, cemented and overdenture retained restoration, other superstructure and instruments for prosthetics that used when the SM-Extra Wide implants is surged are same with each standard type of DIO SM Implant System.

10. Packing / Labeling / Product Information

In a clean room that is Class 10,000 or less, put the product into a plastic ampoule, and then put the plastic ampoule in a pet container, then sealed the pet container with Tyvek®. SM-Extra Wide(RBM) Implant System will be packaged.

11. Intended Use

SM-Extra Wide(RBM) Implant Fixture is intended to be surgically placed in the maxillary or mandivular molar areas for the purpose of providing prosthetic support for dental restoration (Crown, Bridges, and overdentures) in partially or fully edentulous individuals. These Fixtures can be used where smaller implants have failed.

12. Substantial Equivalence Comparison

TECHNOLOGICAL CHARACTERISTIC COMPARISON

	Subject Device	Predicate Device
Manufacturer Name	DIO Department, DSI, Inc.	MegaGen Co.,Ltd.
Device Name	SM-Extra Wide(RBM) Implant System	Rescue Dental Internal Implant System
510(k) Number	Not available yet	K063216
Intended Use	Same with predicate device	The Rescue Internal Implant is intended to be surgically placed in the maxillary or mandivular molar areas for the purpose of providing prosthetic support for dental restoration (Crown, Bridges, and overdentures) in partially or fully edentulous individuals. These Fixtures can be used where smaller implants have failed.
Material	CP Ti Gr4	CP Ti Gr4
Design	Internal Type and Morse Tapered	Internal Type and Morse Tapered
Screw Threads	YES	YES
Implant Diameters(mm)	5.9/6.4/6.9	6.0/6.5/7.0/8.0
Implant Lengths(mm)	7/8.5/10	7.0-12.5
Surface Treatment	RBM (Resorbable Blast Media)	RBM (Resorbable Blast Media)
Sterilization Method	GAMMA	GAMMA
Attachments	Various abutments and components	Various abutments and components
Product Code	DZE	DZE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2008

DIO Department, DSI, Incorporated
C/O Mr. Hyungick Kim
Manager
DIO, USA
3540 Wilshire Boulevard, Suite 1104
Los Angeles, California 90010

Re: K080128
Trade/Device Name: SM-Extra Wide(RBM) Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: May 9, 2008
Received: May 12, 2008

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indication for Use

510(K) Number (if known): _____

Device Name: SM-Extra Wide(RBM) Implant System

Indications For Use:

SM-Extra Wide(RBM) Implant Fixture is intended to be surgically placed in the maxillary or mandivular molar areas for the purpose of providing prosthetic support for dental restoration (Crown, Bridges, and overdentures) in partially or fully edentulous individuals. These Fixtures can be used where smaller implants have failed.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080128

Prescription Use ✓ AND/OR _____ Over – The-Counter Use
(Part 21 CFR 801 Subpart D) (Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)